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09/402,093 09/29/99 QHSUYE

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BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA VA 22313-1404

EXAMINER

SLOBODYANSKY, E

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/402,093

Applicant(s)
Ohsuye et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on Jul 26, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-27 is/are pending in the application.

Of the above, claim(s) 24 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-23 and 25-27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-27 are pending.

Election/Restriction

Applicant's election with traverse of Group I, claims 1-23 and 25-27, in Paper No. 10 filed July 26, 2001 is acknowledged. The traversal is on the ground(s) that "[t]he traversal is based upon the fact that the instant application is filed under §371" (page 1, last paragraph). And further, "[t]he GLP-1 derivative is obtained from the process of claim 14. These claims are thus all united by the underlying principle of a process for producing a peptide and use of said peptide. Unity of invention thus exists" (ibid). This is not found persuasive because as stated in the restriction requirement mailed June 26, 2001, a method for preparing a peptide using a cell transformed with a DNA encoding a peptide of interest and a helper peptide is known in the prior art as evidenced by US patents 5, 202,239 and 5,670,340 (PCT Search Report and form PTO-1449), for example. GLP-1 is also known in the prior art (for example, the specification, page 2, lines 20-25). Therefore, invention of Group I or invention of Group II as a whole does not make a contribution over the prior art.

37 CFR 1.475 does not provide for multiple products or methods within a single application and therefore unity of invention is lacking with regard to Groups I and II.

The requirement is still deemed proper and is therefore made FINAL.

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Claim 24 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Specification

The specification is objected to because of the following: it recites "RHHHGP[G]" (page 8, for example). If it means an amino acid sequence, it should be identified by the sequence in the sequence in the Sequence Listing. Appropriate correction is required.

Claim Objections

Claim 4 is objected to because of the following informalities: it recites "not" where it appears "no" is intended. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

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to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-23 and 25-27 are directed to a process of making a fusion peptide suing a cell transformed with a vector comprising a DNA encoding thereof. Claims 1-13, 18-21, 23 and 25-27 do not limit a peptide of interest by either structure or function. These claims encompass a genus comprising a peptide of any structure and from any source both naturally occurring and man made. Claims 14-17 are directed to a peptide of interest, GLP-1 derivative.

The specification does not contain any disclosure of the structure of GLP-1 peptide and of the structure and function of all GLP-1 derivatives. The genus of DNAs that comprise the DNA molecules encoding thereof is a large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally and functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a three species of the claimed genus. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the "functionality" of encoding a GLP-1 derivative and fails to provide any structure: function correlation present in all members of the claimed genus. Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art

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cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 1-23 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of making GLP-1 derivative, GLP-1 (7-37), does not reasonably provide enablement for a method of making of any peptide or any GLP-1 derivative. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 1-23 and 25-27 are directed to a genus of a polypeptide of an unknown function or retaining insulintropic activity. While the specification a method of making of GLP-1 derivative, 7-37, it does not provide any guidance as to a process of making

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of a peptide of any function and characteristics. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The state of the art does not allow the predictability of the properties based on the structure. The properties of a peptide of an unknown structure are unpredictable. Therefore, one skilled in the art would require guidance as to how to make a peptide of any function and structure by a claimed process. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
Claims 1-23 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because it appears to be directed to two distinct processes of making two distinct products. It is suggested that the claims are amended to encompass a distinct process. Claims 2-23 and 25-27 are rejected as dependent from claim 1.

Claims 14-17 recite GLP-1 derivatives. There is no art accepted definition of "derivative" rendering the scope of the claims unascertainable.

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Claim 23 recites the limitation "endotoxin" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 18-23 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Tarnowski et al.

Tarnowski et al. (US Patent 5,202,239, form PTO-1449) teach a method for expressing peptides as fusion proteins having a high pI (abstract, column 1, lines 40-58, claims 1-8).

Claims 1-13, 18-23 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Yabuta et al.

Yabuta et al. (US Patent 5,670,340, form PTO-1449) teach a method for expressing peptides as fusion proteins having a s a protective peptide *E. coli* β -galactosidase, used in the present invention (abstract, claims 1-5).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarnowski et al. in view of Bell et al.

The teachings of Tarnowski et al. are outlined above.

Bell et al. teach GLP-1 and its physiological importance.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the method taught by Tarnowski et al. to the expression of GLP-1.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yabuta et al. in view of Bell et al.

The teachings of Yabuta et al. are outlined above.

Bell et al. teach GLP-1 and its physiological importance.

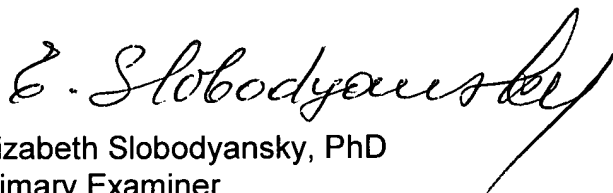
It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the method taught by Yabuta et al. to the expression of GLP-1.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "E. Slobodyansky". The signature is written in black ink and is positioned above the printed name and title.

Elizabeth Slobodyansky, PhD
Primary Examiner

October 5, 2001